

## **REMARKS**

Claims 8-11, 13, 15 and 16 are currently pending. Claims 1-7 were previously canceled. Claims 12 and 14 are canceled in this amendment. Claim 8 has been amended to combine claims 8 and 12. New claim 15 has been added in keeping with the examiner's suggestions. New claim 16 is supported by previously presented claim 13 and paragraph 1 of the specification.

### **Claim Rejections --35 USC Sec. 101 and 112 (page 2-3)**

The examiner states that claims 14 provides for the use of benzocaine in the reduction of the skin irritation caused by an ingredient having a counter-irritation effect used in an analgesic and anti-inflammatory patch as an active ingredient, but, since the claim does not set forth any steps involved in the method/process, it is unclear what the method/process applicant is intending to encompass.

The examiner therefore interpreted claim 14 for the purpose of prior art as follows:  
"[A] method of reducing irritation of the skin caused by an ingredient having a counter-irritation effect used in an analgesic and anti-inflammatory patch as an active ingredient using benzocaine." Applicants have adopted the examiner's interpretation with some grammatical changes as claim 15. Applicants respectfully suggest that new claim 15 overcomes the §§ 101 and 112 rejections to claim 15.

### **Claim Rejections under 35 U.S.C. §102**

The Examiner rejected claims 8-10 and 14 under 35 U.S.C. §102(b) as being anticipated by Juni (US Patent No. 6120792).

The invention of Juni relates to a medicated skin patch for delivering a topical anesthetic to an irritated region of skin includes a bibulous pad for containing and covering the irritated region.

The patch is made out of a material capable of holding a liquid or gel. The anesthetic used in Juni is preferably 10% benzocaine dispersed in a gelled matrix, and patch further comprises a counter-irritant substance such as menthol or capsaicin.

However, please note that adhesive patch of Juni is not aqueous adhesive patch comprising an aqueous poultice material containing 10 to 80 wt% water. Furthermore, in Juni, there is no suggestion or description of using benzocaine together with a counter-irritant to reduce pain or inflammation effectively. It is respectfully presented that the present claims are not anticipated by the Juni reference.

**Claim Rejections --35 USC Sec. 103 (pages 4-5)**

Claim 11-13 were rejected under 35 U.S.C. 103(a), as being unpatentable over Juni (US Patent No. 6120792) as applied to claims 8-10 and 14 above, and further in view of Bernstein (US Patent No. 4997853) and Yamasaki et al. (US Patent No. 7018647).

1) Juni (US Patent No. 6120792)

As mentioned above, the invention of Juni relates to a medicated skin patch for delivering a topical anesthetic to an irritated region of skin includes a bibulous pad for containing and covering the irritated region. Examples of irritation include insect bites, plant irritations, contact dermatitis and minor injuries (col. 1, lines 11-12 of the Juni reference). In contrast, the patch of the present invention can be highly effective for the purposes of reducing pains, such as muscle pain, joint pain, lumbago, shoulder stiffness, fracture pain and other symptoms associated with pain, without unpleasant irritation caused by the counter-irritants themselves itself when topically applied (see paragraph [0006] of the application). As defined in the application (paragraph [0005], “[c]ounter-irritants are used to alleviate the congestion in the deep tissue by taking advantage of their ability to stimulate the skin and cause a slight inflammation.” (Emphasis added.)

Moreover, in the invention of Juni, the topical anesthetic is imbibed in the bibulous pad; that is, the topical anesthetic is absorbed and maintained in the bibulous pad in the case of skin patch of Juni. On the contrary, the present invention relates to an analgesic and anti-inflammatory patch in the form of an aqueous poultice material containing 10 to 80 wt% water comprising benzocaine and an ingredient having a counter-irritation effect as active ingredients. Therefore, the present invention does not

need to use the bibulous pad in which the topical anesthetic is imbibed. Accordingly, the present invention is clearly different from the invention of Juni in the sense that using pad in which the topical anesthetic is imbibed.

Though, in Juni, there is the description that the bibulous pad may also have a counter-irritant substance such as menthol imbibed into it to provide an immediate sensation of warmth when pad is applied (column 3, line 56 to 58), there is no description or suggestion about a counter-irritant effect sufficient to reduce pains.

(2) Bernstein (US Patent No. 4997853)

The invention of Bernstein relates to the treatment of superficial pain syndrome and, in particular, to improved uses of capsaicin to treat these conditions (column 1, line 9 to 11).

In Bernstein, there is the following description:

“Over the past 5 years topical capsaicin has emerged as the treatment of choice for superficial pain syndromes such as postherpetic neuralgia. ... However, from 10% to 30% of patients treated with topical capsaicin experience moderate to serve local reaction, principally, stinging or burning of the skin on initial applications. Such burning may cause some of these patients to discontinue capsaicin use before they can experience pain relief from the treatment.

It has been discovered that incorporating topical anesthetic such as lidocaine and benzocaine into formulations containing capsaicin and then applying such formulations for the initial period of treatment can reduce or even eliminate the painful burning from the application of capsaicin, allowing the patients to continue therapy thereafter without requiring the use of anesthetics” (column 1, line 11 to 34).

Therefore, the invention of Bernstein has the features of reducing or eliminating the side effect of capsaicin such as stinging or burning of skin during the treatment of

choice for superficial pain syndromes such as post-herpetic neuralgia by using anesthetic such as lidocaine and benzocaine.

To the contrary, the present invention provides an analgesic and anti-inflammatory patch that has a high anti-inflammatory and analgesic effect while reducing an unpleasant irritation upon an application. For these purposes, the patch of the present invention contains an ingredient having a counter-irritant effect such as l-menthol, methyl salicylate and so on, along with benzocaine as active ingredient, so that it causes less skin irritation than the conventional patch preparation containing counter-irritants, while still exhibiting a desired anti-inflammatory and analgesic effect (q.v., Test Examples 1 to 3 of the present specification).

These effects are not described or suggested in the Bernstein reference. There is nothing in Bernstein that would suggest use of any counter-irritant other than capsaicin or for using counter-irritants together with benzocaine to treat muscle or joint pain. The effectiveness of the poultices according to the invention in treating, respectively, joint pain and lumbago is demonstrated in Test Examples 2 and 3. The composition of Bernstein is not used for the same purpose.

Furthermore, Bernstein fails to disclose a patch in the form of an aqueous poultice material containing 10 to 80 wt% water.

(3) Yamasaki et al. (US Patent No. 7018647)

The invention of Yamasaki et al. relates to an external skin patch having greatly improved antiphlogistic analgesic effects which has a drug reservoir layer comprising a drug-containing base containing an adhesive gel base which contains a water soluble polymeric material, a crosslinking agent, water and humectant as its essential components and local anesthetic and non-steroidal antiphlogistic analgesic agent as medicinal components.

The purpose of the invention of Yamasaki et al. is to reduce a pain accompanied by inflammation such as chronic arthro-rheumatism, arthrosis deformans or low back pain by the anti-inflammatory effect as well as the local analgesic effect.

The invention of Yamasaki et al. uses local anesthetic and non-steroidal antiphlogistic analgesic agent as medicinal components. Therefore, the present invention is in one way opposite from the invention of Yamasaki et al. The present application uses a slight inflammatory agent, the counter-irritants (see paragraph [0005] of the application), while the Yamasaki uses known anti-inflammatory agents.

Furthermore, Yamasaki et al. fails to disclose a patch in the form of an aqueous poultice material containing 10 to 80 wt% water. Moreover, Yamasaki et al. neither discloses nor suggest the use of a counter-irritant, together with benzocaine, for effectively reducing pain or inflammation. Therefore, even through the combination of the teachings of these documents, the person skilled in the art would not create the present invention, and consequently, applicants respectfully maintain that the subject matter of the present invention is not obvious over Juni and further in view of Bemstein and Yamasaki et al.

Applicants respectfully request that a timely Notice of Allowance be issued in this case.

### CONCLUSION

If the Examiner has any questions or suggested Examiner's amendments, the Examiner is respectfully requested to call the undersigned.

The Commissioner is hereby authorized to charge any additional fees, or to credit any overpayment, to Deposit Account No. 50-3195.

Respectfully submitted,

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